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K111232

Montreal, January 16th, 2012

## 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

**Applicant:** Pega Medical Inc.
1111 Autoroute Chomedey
Laval, Quebec H7W 5J8
Canada

**Contact Person:** Ariel R. Dujovne

**Proprietary Name**: GAP Endo-Exo Medullary System

**Common Name:** Intramedullary Nail

**Device Classification:** Class II

**Classification Name:** Rod, Fixation, Intramedullary And Accessories 21 CFR 888-3020

**Device Product Code:** HSB

**Establishment Registration Number:** 9048931

**Intended Use**: The GAP Endo-Exo Medullary System is indicated as a temporary implant to assure alignment, stabilization and fixation of: long bones that have been surgically prepared (osteotomy) for correction of deformities or fractures caused by trauma or disease. The GAP Endo-Exo Medullary System is used for pediatric patients (child and adolescent) age 2 to 21. It can be used to correct the following conditions:

- Diaphyseal facture of the femur, tibia and humerus
- Fractures of the femoral neck
- Subtrochanteric, intertrochanteric and combination fractures
- Correction of deformities (OI, Coxa vara, Coxa valga)
- Nonunions and malunions

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**Description:** The GAP Endo-Exo Medullary System consists of an intramedullary cannulated nail linked to various types of plates via lag and/or mechanical screws creating a combined Endoamedullary/ Exomedullary osteosythesis device. 3 and 4mm cortical screws are used to secure the nail to the bone.

**Basis for substantial equivalent:**

The GAP Endo-Exo Medullary System is claimed to be substantially equivalent in design and function to the following predicate devices:

1. Fassier-Duval Telescopic IM System (Stainless steel or Ti pediatric nail), Pega Medical Inc. (K041393/K020885)
2. Synthes Adolescent Lateral Entry Femoral Nail System (Ti alloy nail and screws), Synthes USA. (K070843)
3. Titanium Pediatric Femoral Nail (Ti alloy nail and screws) Biomet Inc. (K993956)

The intended uses of these devices are the same as the GAP Endo-Exo Medullary System

**Summary of Technologies**: The technological characteristics of the GAP Endo-Exo Medullary System are the same or similar to the ones of the predicate devices.

**Biomechanical Testing**: A static 4 point bending test, torsion test and 4 point bending fatigue test based on the ASTM standard F 1264 "Standard Specifications and Test Method for Intramedullary Fixation Devices" were performed to demonstrate safety. The results indicated that the GAP Endo-Exo Medullary System is functionally safe for its intended use.

**Clinical Testing**: No clinical testing was provided as a basis for substantial equivalence. A clinical data report based on equivalent products can be found in Appendix H.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pega Medical Inc
% Mr. Ariel R. Dujovne
1111 Autoroute Chomedey
Laval, Quebec H7W 5J8
Canada

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Re: K111232
Trade/Device Name: GAP Endo-Exo Medullary System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 16, 2012
Received: January 18, 2012

Dear Mr. Dujovne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number (if known): K111232

Device Name: **GAP ENDO-EXO MEDULLARY SYSTEM**

Indications for Use:

The GAP Endo-Exo Medullary System is indicated as a temporary implant to assure alignment, stabilization and fixation of: long bones that have been surgically prepared (osteotomy) for correction of deformities or fractures caused by trauma or disease. The GAP Endo-Exo Medullary System is used for pediatric patients (child and adolescent) age 2 to 21. It can be used to correct the following conditions:

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- Nonunions and malunions

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __no_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111232